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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/740,660	12/18/2000	Ganapati R. Mauze	10004415-1	3498

7590 01/07/2004

AGILENT TECHNOLOGIES
Legal Department, 51U-PD
Intellectual Property Administration
P. O. Box 58043
Santa Clara, CA 95052-8043

EXAMINER

CEPERLEY, MARY

ART UNIT PAPER NUMBER

1641

DATE MAILED: 01/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/740,660

Applicant(s)

MAUZE ET AL.

Examiner

Mary (Molly) E. Ceperley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,8,10,11,13-21,23-27 and 32-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,8,10,11,13-21,23-27 and 32-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

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1) A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 15, 2003 has been entered.

2) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3) Although specific claims are cited in the rejections below, these rejections are also applicable to all other claims in which the noted problems/language occur.

4) The amendment filed October 15, 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the change of the term "the acceptor molecules of the surface coating" to "the donor molecules of the surface coating" at page 4, lines 14-17 of the specification. The proposed change would be inconsistent with the previous paragraph of page 4 of the specification, which states that the "surface coating" includes "elements capable of acting as energy acceptors"; page 4, line 17 which refers to "the acceptor molecules of the surface coating"; page 4, line 30 which refers to "the donor surface"; and page 6, lines 18 which states that "surface coating 2 must be capable of acting as a donor".

Applicant is required to cancel the new matter in the reply to this Office Action.

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5) Claims 1-5, 8, 10, 11, 13-21, 23-27 and 32-49 are rejected under 35 USC 112, first paragraph, as not corresponding to the enabling written disclosure of the invention as it is set forth in the specification. As related to claim 1 (currently amended), the description of the invention requires the following: **1)** that the "surface coating" of (b) contain a fluorescent donor molecule; **2)** that the "protection layer" of (c) additionally possess the property of protecting said surface coating from a collisional quencher molecule; and **3)** that a "fluorescent acceptor molecule" be present outside the transparent protection layer. See the following sections of the specification:

Page 2, lines 21-24 wherein "the proximity of bound biomolecules to the protection layer allows for energy transfer from donor molecules that are inside of the transparent protection layer to the acceptor molecules that are outside the transparent protection layer". See also, page 8, lines 14-16;

Page 6, line 18 wherein "surface coating 2 must be capable of acting as a donor";

Page 4, lines 24-26 wherein "the surface with the adsorbed donor layer is then coated with a layer of optically transparent matrix such as sol gel, which also acts as a diffusion barrier to quenchers such as oxygen."

Page 4, lines 28-29 wherein the "the transparent barrier allows fluorescence emission for the donor to radiate through it".

Page 2, lines 21-24: "allows for energy transfer from donor molecules that are inside of the transparent protection layer to the acceptor molecules that are outside the transparent protection layer".

Without the above-cited limitations, the claims do not define the invention which is disclosed in the instant specification, i.e. a composition useful in a FRET assay. See also, paragraph **5)** of the December 16, 2002 Office action.

6) Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

There is no antecedent basis in either claim 8 or claim 1 for the claim 13 term "said fluorescent donor molecule".

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7) Claims 21, 26 and 33-35 are objected to as being duplicates of claim 1. The "for use in" limitation of claims 21, 26 and 33-35 does not further distinguish the claimed compositions from the composition of claim 1.

8) Claims 1, 4, 5, 8, 21, 25-27, 32-38 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Hainfeld et al (U.S. 5,521,289) for the reasons of record (see paragraph 5) of the May 19, 2003 final rejection). A description of the Hainfeld et al patent appears in paragraph 8) of the December 26, 2002 Office action.

Applicant's arguments filed October 15, 2003 have been fully considered but they are not persuasive. As set forth in paragraph 5) of the final rejection, claim 1 of the instant application is anticipated by the composition of Hainfeld et al. Applicant argues that the claimed composition differs from the composition of the reference based on a method of use distinction, namely, that the polymer coating of Hainfeld et al is not a "protection layer that encapsulates a surface coating" but is rather a polymer coating to which ligands may be attached. This argument is unconvincing for the reason that what is being claimed is a composition and the actual structures of both the prior art and claimed compositions are the same, independent of any method of use distinction, as described in paragraph 5) of the final rejection. It is further noted that instant claim 18 includes the limitation that the "protection layer" (which may be a polymer: see the instant specification at page 9, lines 3-4; page 8, lines 22-25) is modified with "functionalities" such as "hydroxyl, carboxyl and protonated amines" as similarly described by Hainfeld et al at col. 7, lines 61-64. The limitations of instant claim 47 are considered to be inherently present in the composition of Hainfeld et al. The addition of a ligand to the protection layer (instant claim 37) is described by Hainfeld et al at col. 7, lines 61-64 (see the functionalized polymer coating to which ligands are covalently attached). Hainfeld et al do not disclose any donor-acceptor FRET combination. The addition of the claim limitations described in paragraph 5) above would overcome this prior art rejection.

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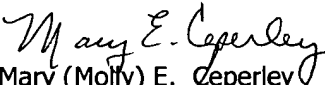
9) Claims 11 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hainfeld et al (U.S. 5,521,289) for the reasons set forth in paragraph **6)** of the final rejection and in paragraph **8)** directly above. Applicant's arguments regarding the Hainfeld et al reference are addressed in paragraph **8)** above.

10) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary (Molly) E. Ceperley whose telephone number is (703) 308-4239. The examiner can normally be reached from 8 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le, can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556 or (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

January 06, 2004


Mary (Molly) E. Ceperley
Primary Examiner
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